REMARKS

Claim Status

Claims 1-14, 16, and 18-40 are pending in the subject application.

Rejection Under 35 U.S.C. § 102(e)

On page 2 of the Office Action, the Examiner rejected claims 1-4, 16, 18-40 as being anticipated by Püschl, et al., WO 03/029232 ("'232 reference"). The Examiner alleged that the '232 reference has common inventors with the instant application, and that based upon the earlier effective U.S. filing date of the '232 reference, it constitutes prior art under 35 U.S.C. 102(e).

The Examiner then suggested that this rejection might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application, and thus, is not an invention "by another', or by an appropriate showing under 37 CFR 1.131.

In response in an attempt to advance the prosecution of the subject application, but without conceding the correctness of the Examiner's position, applicants submit a Declaration of Inventor Ask Püschl under 37 C.F.R. 1.132, attached hereto as **Exhibit A**, to overcome the rejection under 35 U.S.C. 102(e).

Accordingly, applicants respectfully request reconsideration and withdrawal of this rejection.

Rejection under 35 U.S.C. § 103(a)

On page 2 of the Office Action, the Examiner rejected claims 1-14, 16, and 18-40 as being unpatentable over Martin, et al. ("Martin"), J. Med. Chem. (1979), vol. 22(11), pp. 1347-1354, in view of Silverman, "The Organic Chemistry Of Drug Design and Drug Action", (1992), San Diego; Academic Press, page 19 ("Silverman").

The Examiner alleges that Martin teaches similar compounds, their composition and method of use for treating affective disorders; and that the difference between the instant invention and that of Martin is that in compounds of the prior art, applicants replaced $-CH_2-$ with –S-. The Examiner further alleges that some of the compounds of Martin are 3° amines instead of the 2° amines of the instant compounds, and some are positional isomers of the instant compounds. The Examiner also alleges that Silverman teaches that replacement of $-CH_2-$ with –S- in a compound is expected to produce compounds having similar biological activity (bioisosterism).

The Examiner then concludes that the instant invention is prima facie obvious from the teachings of Martin and Silverman because one of ordinary skill in the art would have known to replace $-CH_2-$ with –S- in the compounds of Martin at the time the instant invention was made, and that the motivation is from knowing that $-CH_2-$ with –S- are bioisosteres equivalents.

In response, applicants note that the Examiner alleges that in all cases a prior art disclosure of a positional isomer renders an applicant's claims *prima facie* obvious.

Applicants respectfully traverse in view of the level of unpredictability that exists in the pharmaceutical arts. The Examiner provides no rationale as to why the same safety and efficacy profile would be expected from Martin. Martin does not teach or even mention whether the compounds disclosed therein would be improved, remain the same, or be made worse if the compounds were modified to adjust the position of

the nitrogen in the six member ring. The rejection does not fill, nor explain, that gap in the prior art.

Indeed, the Supreme Court in KSR v. Teleflex has recently reaffirmed the importance of avoiding mere conclusions as the only evidence to sustain a rejection under 35 U.S.C. § 103. KSR International Co. v. Teleflex Inc., 550 U.S. __ (2007) ("rejections on obviousness grounds cannot be sustained on mere conclusory statements").

In addition, applicants respectfully traverse that the substitution of a methylene linkage for the Sulfur linkage in Martin would have been *prima facie* obvious. As a basis for this traversal, applicants incorporate all of the arguments set forth above with respect to the positional isomer hereinabove.

Further, the extremely generic disclosure of Silverman does not remedy the previously identified deficiencies. For example, Silverman only mentions in a single sentence the possibility of "broadly similar biological properties". This one statement does not begin to remove the current level of unpredictability in drug discovery that exists. Many factors naturally affect pharmacological properties of compounds, including the structure of the overall compound, the exact nature of the biological target(s) (in applicants' invention there are three), and the nature of and complications associated with the disease. Martin and Silverman, and the rejection, specifically address none of these factors. Moreover, Silverman's use of "broadly" or "broadly similar" in fact highlights the unpredictability of the pharmaceutical arts since it goes toward the fact that bioisosteres have general or wide similarity. Consequently, one skilled in the art would not expect the replacement of the –S- group of Martin with a $-CH_2-$ group to be advantageous.

Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this rejection.

Non-Statutory Obviousness-Type Double Patenting

On page 5 of the Office Action, the Examiner rejected claims 1-14, 16, and 18-40 on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. patent No. 7,138,407, claims 1-18 of U.S patent 7,148,238, and claims 1-29 of U.S. 7,144,884.

In response in an attempt to advance the prosecution of the subject application, but without conceding the correctness of the Examiner's position, applicants submit a terminal disclaimer, attached hereto as **Exhibit B**, in compliance with 37 C.F.R. 1.321(c) to overcome the obviousness-type double patenting rejection. Accordingly, applicants respectfully request reconsideration and withdrawal of this rejection.

The terminal disclaimer fee, $ 130.00, required under 1.20(d) is being paid currently with this response. The Commissioner is hereby authorized to charge any additional fee or underpayment thereof, or credit any overpayment, to deposit account no, 503201.

On page 5 of the Office Action, the Examiner provisionally rejected claims 1-14, 16, 18-40 on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1-12, 14, 16-34 of co-pending Application No. 11/551,188.

In response, without conceding the correctness of the Examiner's position and upon the indication of allowable subject matter in connection with the present application, applicants will consider filing a terminal disclaimer to overcome the obviousness-type double patenting rejection.

CONCLUSION

In view of the foregoing, applicants believe the claims are in condition for allowance and respectfully request a notice of the same.

If a telephone interview would be of assistance in advancing prosecution of the above-identified application, Applicants invite the Examiner to telephone the undersigned at the number provided below.

Respectfully submitted,

/Margaret M. Buck, Reg. # 54,010/

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EXHIBIT A

Case 433-US-PCT
Conf. No. 2039

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Ask Püschl, et al.		
Serial No.:	10/551,869	Examiner:	Taofiq A. Solola
Filed:	October 31, 2006	Group Art Unit:	1625
For:	4-(2-PHENYLSULFANYL-PHENYL)-1,2,3,6-TETRAHYDROPYRIDINE DERIVATIVES AS SEROTONIN REUPTAKE INHIBITORS		

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SIR:

DECLARATION OF INVENTOR ASK PÜSCHL UNDER 37 C.F.R. § 1.132

I, Ask Püschl, hereby declare as follows:

1. Benny Bang-Andersen ("BAN"), Thomas Ruhland ("TR"), Kim Andersen ("KIA") and I conceived of, and reduced to practice, the invention claimed in the above-identified patent application, i.e., an invention relating to 4-(2-phenylsulfanyl-phenyl)-1,2,3,6-tetrahydropyridine derivatives useful in the treatment of affective disorders, as to which we have been named co-inventors.

2. At the time we made the invention claimed in the subject application each of us was employed by H. Lundbeck A/S, the assignee of the application.

3. Subsequent to our conception of the phenyl-piperazine derivatives invention disclosed in International Patent Publication No. WO 03/029232, in which certain aspects of the present invention were included, my co-inventors (BAN, TR and KIA) and I

collaborated with Morten Jørgensen, Karsten Juhl and Jan Kehler in work concerning the present invention, which led to our claiming the present application.

5. Thus, all disclosures concerning the present invention disclosed in International Patent Publication No. WO 03/029232 are disclosures by inventors named in the present application.

7. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that any such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Ask Püschl

Ask Püschl

2 Juni 2008

Date

EXHIBIT B

PTO/SB/26 (01-08)
Approved for use through 02/29/2008. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A "PRIOR" PATENT	Docket Number (Optional) 433-US-PCT

In re Application of: **Ask Püschl, et al.**

Application No.: **10/551,869**

Filed: **October 31, 2006**

For: **4-(2-PHENYLSULFANYL-PHENYL)-1,2,3,6-TETRAHYDROPYRIDINE DERIVATIVES AS SEROTONIN REUPTAKE INHIBITORS**

The owner*, H. LUNDBECK A/S, of 100 percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of **prior patent Nos.** U.S. 7,138,407, U.S. 7,148,238 and U.S. 7,144,884 as the term of said prior patents is defined in 35 U.S.C. 154 and 173, and as the term of said **prior patents** is presently shortened by any terminal disclaimer. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the **prior patents** are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the owner does not disclaim the terminal part of the term of any patent granted on the instant application that would extend to the expiration date of the full statutory term as defined in 35 U.S.C. 154 and 173 of the **prior patents**, "as the term of said **prior patent[s]** is presently shortened by any terminal disclaimer," in the event that said **prior patents** later:

expires for failure to pay a maintenance fee;
is held unenforceable;
is found invalid by a court of competent jurisdiction;
is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321;
has all claims canceled by a reexamination certificate;
is reissued; or
is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.

Check either box 1 or 2 below, if appropriate.

1. ☐ For submissions on behalf of a business/organization (e.g., corporation, partnership, university, government agency, etc.), the undersigned is empowered to act on behalf of the business/organization.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

2. ☑ The undersigned is an attorney or agent of record. Reg. No. 54,010

/Margaret M. Buck, Reg. # 54,010/ — Signature
06/03/2008 — Date

Margaret M. Buck, Esq.

201-350-0790 — Telephone Number

☑ Terminal disclaimer fee under 37 CFR 1.20(d) included.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

*Statement under 37 CFR 3.73(b) is required if terminal disclaimer is signed by the assignee (owner).
Form PTO/SB/96 may be used for making this certification. See MPEP § 324.